

RECEIVED AT DRUG SAFETY SURVEILLANCE

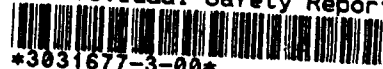


19-FEB-1998-0660

McNEILMcNEIL CONSUMER PRODUCTS
FORT WASHINGTON, PA

Page ____ of ____

Individual Safety Report



3031677-3-00

A. Patient information

| | | | |
|--|---|----------------------------------|-----------------------------------|
| 1. Patient Identifier Case 200 In confidence | 2. Age at time of event: or 75 yrs Date of birth: | 3. Sex () female (X) male | 4. Weight unk lbs or kgs |
|--|---|----------------------------------|-----------------------------------|

B. Adverse event or product problem

| | |
|--|--|
| 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) | |
| 2. Outcomes attributed to adverse event (check all that apply) | () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other: |
| (X) death (mo/day/yr) unknown | |
| () life-threatening | |
| (X) hospitalization - initial or prolonged | |

| | |
|---|--|
| 3. Date of event (mo/day/yr) unknown | 4. Date of this report (mo/day/yr) 02/09/98 |
|---|--|

5. Describe event or problem

Case # 200 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

FEB 11 1998

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

| | |
|---|--|
| 1. Name (give labeled strength & mfr/labeler, if known) #1 unknown acetaminophen product #2 | |
| 2. Dose, frequency & route used #1 unknown dose, po #2 | 3. Therapy dates (if unknown, give duration) from/to for best estimate #1 previous 2-3 days #2 |
| 4. Diagnosis for use (indication) #1 "didn't feel well" #2 | |
| 5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A | |
| 6. Lot # (if known) #1 Unknown #2 | 7. Exp. date (if known) #1 Unknown #2 |
| 8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A | |
| 9. NDC # - for product problems only (if known) - - | |
| 10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by [redacted] | |

G. All manufacturers

| | | |
|--|--|--|
| 1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034 | | 2. Phone number 215-233-7820 |
| 4. Date received by manufacturer (mo/day/yr) 01/30/98 | | 3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other: |
| 6. IND, protocol # | 5. (A) NDA # 17-552 IND # PLA # pre-1938 () Yes OTC product (X) Yes | |
| 7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up # | 8. Adverse event term(s) OVERDOSE STUPOR LIVER FAILURE KIDNEY FAILURE COAGULATION DIS DEATH | |
| 9. Mfr. report number 0929699A | | |

E. Initial reporter

| | | |
|--|----------------------------|---|
| 1. Name, address & phone # [redacted] MD [redacted] Centers Suite [redacted] Avenue [redacted] | | |
| 2. Health professional? (X) Yes () No | 3. Occupation physician | 4. Initial reporter also sent report to FDA () Yes () No (X) Unk |

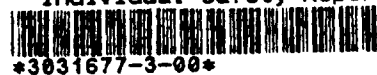


Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



19-FEB-1998-0661



3031677-3-00

FATALITY: 1996

Case Number: 200

Age: 75 yrs

Substances: Acetaminophen

Chronicity: Chronic

Route: Ingestion

Reason: Ther error

Pre-Hospital Arrest? No

A 72⁵-year-old man with a history of alcoholism presented to the ED unresponsive. He had been taking an unknown amount of acetaminophen over the course of the previous 2-3 days because he didn't feel well. By the time the poison center was consulted, the patient was intubated and unresponsive with evidence of liver and renal failure. His laboratory studies revealed, ethanol, 50 mg/dL; acetaminophen, 32 mg/L; AST, 8000 U/L; creatinine, 4 mg/dL; BUN, 24 mg/dL; and an INR of 7.2. Therapy with N-acetylcysteine was recommended. The patient expired 19 hours after poison center consultation. It is unknown if the patient ever received NAC, and also unclear exactly how long the patient was in the hospital prior to death.